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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,858	11/20/2001	A. Dean Sherry	UTAD-0001	1523

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,858	SHERRY ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *15 and 19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 16-18, and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges the amendment filed 2/24/04 wherein the specification was amended. In addition, it is noted that claims 1-4, 10, 11, and 16 have been amended.

Note: Claims 1-36 are pending.

WITHDRAWN CLAIMS

2. Claims 15 and 19-22 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments filed 2/24/04 to the rejection of claims 1-14, 16-18, and 23-36 made by the Examiner under 35 USC 102, 103, and 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

I. The 112 rejection over claim 16 is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

II. The rejection of claims 1-14, 16-18, and 23-36 is MAINTAINED under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In the office action mailed 2/3/04, the Examiner was requesting clarification in regards to the phrase 'R1 includes organic substitutents'. Specifically, the Examiner's

was inquiring if Applicant intended to incorporate Markush terminology. In addition, the Examiner argued that the phrase contained 'open' terminology (i.e., 'includes' and 'comprising') and may include unnamed ingredients.

It duly noted that Applicant intended to include the phrases 'comprising organic substitutents' and 'R1 includes organic substitutents'. In addition, it is noted that Applicant states that the phrases are not indefinite.

The Examiner would like to reiterated that the phrases are vague and indefinite, not only because it is unclear what is included in Applicant's phrases, but also the terms 'including organic substitutents' indicate that Applicant is defining R1 as having at least two selections. For example, 'wherein R1 includes organic substitutents' could very well be interpreted as R1 includes all organic substitutents and non-organic substitutents (i.e., halogens, hydrogen, etc.). Thus, the phrase is indefinite because it is unclear what other substitutents are present in the grouping. Furthermore, it is noted that in Applicant's specification paragraphs 0055 & 0056 of the PG Pub document of the instant invention included with this action, it is disclosed that R1 and R2 comprise organic substitutents. However, in the preferred embodiments R1 and R2 are hydrogen. Thus, Applicant obviously intended that neither R1 nor R2 would only be organic substitutents.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

103 Rejection

The rejection of claims 1-14, 16-18, and 23-36 under 35 USC 103(a) as being unpatentable over Aime et al (Chem. Commun., 1999, 1047-1048) in view of Ward et al (J. Magnetic Resonance, March 2000, Vol. 143, pp. 79-87) and Dunard et al (J. Am. Chem. Soc., February 2000, Vol. 122, pp. 1506-1512) is MAINTAINED.

Applicant's arguments may be summarized as (1) Aime et al does not suggest each and every limitation present in the instant invention. (2) Aime et al does not provide teaching or suggestion that a bound water molecule associated with either Eu-L3a or Gd-L3a has a $\Delta\omega \cdot \tau \geq 1$ and $\Delta\omega \geq 6$ ppm. (3) The combination of references is improper because a person of ordinary skill in the art would not be motivated to find/add to Aime or Dunard the teachings of Ward since Ward rejects the use of metal based contrast agents.

First, Applicant is reminded that if every limitation of the instant invention is present in Aime et al, then the document would anticipate the instant invention, not render it obvious. Thus, as set forth in the previous office action mailed 2/3/04, the cited references were combined because they disclose a contrast agent comprising a tetraazacyclododecane ligand structure.

Secondly, a skilled practitioner would recognize that structurally similar contrast agents would inherently have similar/same properties. Thus, since the complex of the prior art is encompassed by Applicant's invention, it would be obvious that the properties associated with Applicant's contrast agent would also be present in the compounds of the prior art.

Thirdly, the rejections were combined on the basis that all of the references in some way disclose a DOTA complex that is encompassed by the formulae in independent claims 1, 10, and 24. The differences between the instant invention and the prior art are that the prior art does not specifically state that the water molecule having has a $\Delta\omega \cdot \tau \geq 1$ and $\Delta\omega \geq 6$ ppm. However, as previously stated, it would have been obvious that structurally similar contrast agents would inherently have similar/same properties. Furthermore, a skilled practitioner in the art would recognize that the physical/chemical properties of a compound are inseparable from the compound. In other words, it is unclear how/why the compounds of the instant invention which are encompassed by the prior art lack the same/similar properties thereof.

Note: The 103(a) rejection was modified to include the claims from the previous 102 rejection since Applicant amended the claims to overcome the 102 rejection and the claims are now rejectable under 103(a).

COMMENTS/NOTES

4. Once again, it is noted that Applicant's elected species was searched and no prior art was found which could be used to reject the elected species. Thus, the search was expanded to the species wherein R, R', R", and R'" are CR1H-CO-NH-CH2-R2; R1 is H; and R2 is CH2COOEt (hereafter represented as EXP#1). The search was not further expanded because prior art was found which could be used to reject Applicant's claims.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

May 17, 2002